Life Spine®

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510(k) Summary

Life Spine Facet Screw Spinal System

k090865

Submitted By:

Life Spine
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JUN 26 2009

510(k) Contact:

Mr. Murali Audipudy
Life Spine
2401 W. Hassell Road, Suite 1535
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Telephone: 847-884-6117
Fax: 847-884-6118

Date Prepared: March 27, 2009

Trade Name: Life Spine Facet Screw Spinal System

Product Code: MRW, Facet Screw Spinal Device

Classification: Unclassified

Predicate Device: NuVasive™ Triad™ Facet Screw System (K020411)

Device Description:

The Life Spine Facet Screw Spinal System is a temporary, titanium alloy (6AL-4V-ELI per ASTM F 136), screw and washer system comprised of a variety of sizes of non-sterile, single use implantable components. The facet screw system consists of broad-headed, partially threaded screws designed to compact juxtaposed facet articular processes to enhance spinal fusion and stability.

Intended Use of the Device:

The Life Spine Facet Screw System, when properly used, is intended to stabilize the spine as an aid to fusion through bilateral immobilization of the facet joints. The screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. The Life Spine Facet Screw System is indicated for bilateral facet fixation, with or without bone graft, at single or multiple levels, from L1 to S1.

The Life Spine Facet Screw Spinal System is indicated for treatment of any or all of the following: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies), spondylolisthesis, spondylosis, fracture, degeneration of the facets with instability, pseudoarthrosis, and failed previous fusion.

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Material:

Manufactured from medical grade titanium alloy as described by ASTM F136 (Ti 6Al-4V-ELI) implant grade titanium alloy.

Substantial Equivalence:

The Life Spine Facet Screw Spinal System was shown to be substantially equivalent to previously cleared devices in indications for use, design, function, and materials used.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2009

Life Spine, Inc.
% Mr. Murali Audipudy
RA/QA Manager
2401 W. Hassell Rd., Suite 1535
Hoffman Estates, IL 60169

Re: K090865
Trade/Device Name: Life Spine Facet Screw Spinal System
Regulation Number: Unclassified
Regulation Name: N/A
Regulatory Class: Unclassified
Product Code: MRW
Dated: March 27, 2009
Received: March 30, 2009

Dear Mr. Audipudy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) number (if known): K090865

Device Name: Life Spine Facet Screw Spinal System

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Prescription Use _x_	And/Or	Over-the-Counter Use ____
(Part 21 CFR 801 Subpart D)		(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(EXT for MKM)
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090865